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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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10/582,695

03/21/2007

David C. Greenspan

13791-23

6560

45473

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03/15/2011

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EXAMINER

SUTTON, DARRYL C

ART UNIT

PAPER NUMBER

1612

MAIL DATE

DELIVERY MODE

03/15/2011

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|--------------------------------------|---|--|
| Office Action Summary | Application No. 10/582,695 | Applicant(s) GREENSPAN ET AL. | |
| | Examiner DARRYL C. SUTTON | Art Unit 1612 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 January 2011.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-18,35 and 36 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-18,35 and 36 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 01/24/2011 has been entered. New claims 35 and 36 have been added. Claims 19-34 have been cancelled.

Applicant's arguments filed 01/24/2011 have been fully considered. Rejections and/or objections not reiterated from previous Office Actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set of rejections and/or objections presently being applied to the instant application.

Claim Rejections - 35 USC § 103

Claims 1-18, 35 and 36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gates (US 5,882,630) in view of Stoors (US 6,190,643).

Gates teaches non-aqueous dentifrice compositions comprised of a carboxyvinyl polymer such as a Carbopol 974P, glycerin, polyethylene glycol, a thickening silica, and

Art Unit: 1612

abrasive silica (Abstract, column 4, line 37 - column 5, line 43). The dentifrices contain other agents conventionally used in dentifrice formulations such as anti-plaque agents and anti-calculus agents, i.e. anti-tartar agents in amounts of from 0.001 to 5% (column 3, lines 41-47). The pH of the invention when diluted with water should be less than 8.0 (column 4, lines 17-20).

Gates does not teach bioactive glass.

Stoors teaches a method and compositions for reducing the viability of detrimental oral microorganisms in an individual comprising subjecting the individual's oral cavity to a bioactive glass, the average size of which is less than 100 μm ; the methods include prevention of gingivitis in an individual and for whitening or mechanically cleaning teeth (Abstract and column 2, lines 52-56). Said methods are due to the reduction of the viability and thus the decrease of the number of detrimental oral micro-organisms; and bioactive glass has anti-plaque activity (column 2, lines 11-15, column 3, lines 41-50 and column 7, lines 27-39), i.e. bioactive glass has antimicrobial activity which helps in the prevention of gingivitis. Preferably the average particle size of bioactive glass is about 20 μm or less (column 2, lines 61-64, column 3, line 56).

Stoors does not teach a non-aqueous composition.

Generally, it is *prima facie* obvious to select a known material for incorporation into a composition, based on its recognized suitability for its intended use. See MPEP 2144.07. Accordingly, it would have been obvious to use the bioactive glass of Stoors as the anti-plaque and anti-tartar compound in the compositions of Gates.

Gates does not teach the specific amount of bioactive glass. The prior art does not disclose the exact claimed values, but does overlap: in such instances even a slight overlap in range establishes a *prima facie* case of obviousness. In re Peterson, 65 USPQ2d 1379, 1382 (Fed. Cir. 2003). Gates teaches from 0.001 to 5% by weight of anti-plaque agents, i.e. bioactive glass, versus about 0.25 to about 10% and about 2 to about 5% of instant claims 1, 10 and 18.

In regard to claims 2, 3, 11 and 12, the compositions of suggested by combining Gates and Stoor are dentifrices, i.e. toothpastes. The method of brushing teeth for 2 minutes is generally recommended by dentists. Accordingly, it would have been obvious to brush with the compositions for more than 30 seconds and for about 30 seconds to about 2 minutes.

Applicant argues that Stoor teaches an aqueous composition containing 40-80% of bioactive glass. This teaching would not be commercially viable since such a composition which is taught to be applied for long periods of time, would have elevated pH levels and would be irritating to the oral tissues. Therefore, one of skill reading Stoor would not have arrived at the instant method which uses an anhydrous formulation with significantly lower amounts of bioactive glass to achieve its efficacy.

The Examiner disagrees.

As discussed above, Gates clearly discloses from 0.001 to 5% of

Art Unit: 1612

anti-plaque/anti-tartar agents. Furthermore, Gates teaches a preferred pH of the formulation, i.e. less than 8.0. Accordingly, one skilled in the art would be motivated to include the bioactive glass in the composition in the amounts disclosed for anti-plaque/anti-tartar agents and it would have been within the skilled artisan's purview to measure the pH to assure that the disclosed pH requirement of Gates is met. The skilled artisan would reasonably expect that the amount of bioactive glass in an aqueous composition would not be the same as the amount required for an anhydrous composition. Portions of an aqueous composition would reasonably be expected to be washed away in saliva before the actives perform their activity on the teeth, thus requiring a larger amount of active than an anhydrous composition.

All claims are rejected.

Conclusion

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Art Unit: 1612

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Darryl C. Sutton whose telephone number is (571)270-3286. The examiner can normally be reached on M-Th from 7:30AM to 5:00PM EST or on Fr from 7:30AM to 4:00PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick Krass, can be reached at (571)272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

/Darryl C Sutton/
Examiner, Art Unit 1612

/Frederick Krass/
Supervisory Patent Examiner, Art Unit 1612